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Title: Clinimetric properties of outcome measures in bronchiectasis

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Body: Introduction: In bronchiectasis (BE) there is demand for researchers and regulatory bodies to use robust outcome measures (OM) in clinical trials which have evidence of validity, reliability and responsiveness. Aim: To explore the evidence for clinimetric properties of commonly used outcome measures in BE. Methods: A systematic search of key databases (2000-2010) to identify studies in adults with BE which included the following OM; HRCT, FEV1, Quality of life (QoL), exacerbations (PEx), sputum volume/colour, and sputum inflammatory markers (IL-8 and elastase). Data relating to clinimetric properties was extracted. Results: 68 papers met the inclusion criteria. There was good evidence for all components of validity for HRCT, FEV1, QoL, and with exception of predictive validity for sputum volume/colour and sputum inflammatory markers. There was minimal evidence for validity for PEx. The majority of RCTs in BE included FEV1 (n=9/11) as a key OM however none were able to demonstrate a treatment effect with FEV1. Other research designs (e.g. crossover/cohort studies) were also unable to demonstrate a treatment effect with FEV1. A small number of RCTs (n=5) included the other OMs and some of these studies were able to demonstrate a significant treatment effect (QoL n=2/4, PEx n= 2/4, sputum volume/colour n=1/5 and sputum inflammatory marker n=1/5). Other research designs were also able to demonstrate a treatment effect with these outcomes. There are a small number of studies demonstrating test-retest reliability of these OM. Conclusions: FEV1 is considered to be the primary outcome in clinical trials however current evidence in BE suggests that FEV1 may not be responsive and other outcome measures should be considered.